Introduced by Senator Wolk (Coauthor: Senator Pavley)

(Coauthor: Assembly Member Cristina Garcia)

February 19, 2016

An act to amend Section 1635 of, and to add *and repeal* Article 2.5 (commencing with Section 1642) to Chapter 4.1 of Division 2 of, the Health and Safety Code, relating to tissue banks.

LEGISLATIVE COUNSEL'S DIGEST

SB 1316, as amended, Wolk. Tissue banks: human milk.

Existing law, with certain exceptions, requires a tissue bank operating in California to have a current valid license issued by the State Department of Public Health. Existing law defines a tissue bank as a place, establishment, or institution that collects, processes, stores, or distributes tissue for transplantation into human beings. Existing law defines tissue to include human bodily fluids, and defines transplantation to include by ingestion. The department may suspend or revoke a tissue bank license for specified reasons. A violation of the provisions regulating tissue banks is a misdemeanor.

This bill would define a "human milk tissue bank" as a tissue bank that provides financial compensation to a participating mother for procuring human milk for the purpose of human consumption, and would define a "participating mother" as a woman who provides her human milk to a human milk tissue bank in exchange for financial compensation. The bill would require a human milk tissue bank licensed by the department that collects, processes, stores, or distributes human milk to, among other things, work with lactation support groups to

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provide breastfeeding education and lactation support for a participating mother, from whom the tissue bank procures human milk, as provided. The bill would prohibit a human milk these tissue banks from, among other things, procuring human milk from providing payment to a mother for human milk the tissue bank procures from her within her first 180 90 days postpartum. The bill would require the department to adopt, on or before January 1, 2018, rules and regulations governing-a human milk these tissue bank banks that, at a minimum, are substantially based upon the guidelines of the Human Milk Banking Association of North America for safely procuring, processing, storing, and distributing human milk, and would require a human milk these tissue banks to comply with the latter guidelines until the department adopts those rules and regulations. The bill would provide that a violation of its provisions is not punishable as a misdemeanor under existing law. The bill would provide that its provisions remain in effect only until January 1, 2022.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

- SECTION 1. Section 1635 of the Health and Safety Code is amended to read:
 - 1635. (a) "Donor" means an individual, living or deceased, from whom tissue is removed.
 - (b) "Person" means an individual, corporation, business trust, estate trust, partnership, association, state or local government, or subdivision or agency thereof, or any other legal entity.
 - (c) "Tissue" means a human cell, group of cells, including the cornea, selera, or vitreous humor and other segments of, or the whole eye, bones, skin, arteries, sperm, blood, other fluids, and any other portion of a human body.
 - (d) "Tissue bank" means a place, establishment, or institution that collects, processes, stores, or distributes tissue for transplantation into human beings.
 - (e) "Transplantation" means the act or process of transferring tissue, including by ingestion, from a donor to the body of the donor or another human being.
 - (f) "Department" means the State Department of Public Health.

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(g) "Human milk tissue bank" means a tissue bank that provides a participating mother with financial compensation for procuring human milk for the purpose of human consumption.

(h) "Participating mother" means a woman who provides her human milk to a human milk tissue bank in exchange for financial compensation.

SEC. 2.

SECTION 1. Article 2.5 (commencing with Section 1642) is added to Chapter 4.1 of Division 2 of the Health and Safety Code, to read:

Article 2.5. Human Milk Tissue Banks

- 1642. A human milk tissue bank licensed by the department that collects, processes, stores, or distributes human milk shall do all of the following:
- (a) Comply with the Human Milk Banking Association of North America guidelines for safely procuring, processing, storing, and distributing human milk, until the department adopts rules and regulations pursuant to Section 1642.4.
- (b) Work with local, community-based or hospital-based lactation support groups to provide ongoing breastfeeding education and lactation support for a participating mother *from* whom the tissue bank procures human milk to ensure that her nursing children are adequately nourished by her human milk.
- (c) Disclose to a prospective participating mother who is considering providing human milk to the tissue bank the purposes for which the procured milk is used.
- 1642.2. (a) A human milk tissue bank that collects, processes, stores, or distributes human milk shall not do any of the following:
- (a) Procure provide payment to a mother for human milk procured from a mother her within her first—180 90 days postpartum.
 - (b) Use the term "donor" to describe a participating mother.
 - (c) Use
- (b) A tissue bank that provides payment to a mother for human milk shall not use the term "community benefit" to describe itself or its activities.
- 39 1642.4. Notwithstanding Section 1639, the department shall 40 adopt, on or before January 1, 2018, rules and regulations

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1 governing a human milk tissue bank licensed by the department

- 2 that collects, processes, stores, or distributes human milk that are,
- 3 at a minimum, substantially based upon the guidelines of the
- 4 Human Milk Banking Association of North America for safely procuring, processing, storing, and distributing human milk.
- 6 1642.6. A violation of this article does not constitute a misdemeanor punishable pursuant to Section 1641.
- 8 1642.8. This article shall remain in effect only until January
- 9 1, 2022, and as of that date is repealed, unless a later enacted
- 10 statute, that is enacted before January 1, 2022, deletes or extends
- 11 that date.